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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/005,337  | 12/07/2001  | Patrick Benoit       | 08888.0530          | 9440             |
| 7590  | 06/12/2006  |                      | EXAMINER            |                  |
| Finnegan, Henderson, Farabow,<br>Garrett & Dunner, L.L.P.<br>1300 I Street, N.W.<br>Washington, DC 20005-3315 |             |                      | GIBBS, TERRA C      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1635                |                  |

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/005,337             | BENOIT ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Terra C. Gibbs         | 1635                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 March 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 34-37 and 40-56 is/are pending in the application.
  - 4a) Of the above claim(s) 34-37 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 40-56 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed March 28, 2006.

Claims 1-3, 6, 8, 10, 12, 13, 16, 18, 20, 22, 24, 26, 28, 30, 32, and 38 have been canceled. Claim 40 has been amended.

Claims 34-37 and 40-56 are pending in the instant application.

This application contains claims 34-37 drawn to an invention nonelected with traverse on October 20, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Accordingly, claims 40-56 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 101***

In the previous Office Action mailed January 4, 2006, claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 were rejected under 35 U.S.C. 101 because the claimed invention was directed to non-statutory subject matter. **This rejection is moot** against claims 44, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39 in view of Applicant's Amendment filed March 28, 2006 to cancel these claims. **This rejection is withdrawn** against claims 40-56 in view of Applicant's

Amendment filed March 28, 2006. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 40 to recite, "an isolated polynucleotide".

***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed January 4, 2006, claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 39, and 40-56 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is moot** against claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39 in view of Applicant's Amendment filed March 28, 2006 to cancel these claims. **This rejection is maintained** against claims 40-56 for the reasons of record set forth in the previous Office Action mailed January 4, 2006.

***Response to Arguments***

In response to this rejection, Applicants argue that claim 40 recites both a functional limitation (e.g. inducing expression in cardiac cells *in vivo*) and a structural limitation (e.g. polynucleotides having sequences with at least 93% identity to SEQ ID NO:1). Applicants contend that one skilled in the art would understand how to determine if a given sequence is 93% identical to the whole of SEQ ID NO:1 based on the teachings in the specification of the primary sequence of SEQ ID NO:1. Applicants argue that based on the primary sequence alone, one skilled in the art would readily

understand the metes and bounds of claim 40, thus demonstrating possession of the claimed invention.

Applicant's arguments and contentions have been fully considered but are not found persuasive. The issue, as explained in the previous Office Action, is not that one of skill in the art would understand how to determine if a given sequence is 93% identical to the whole of SEQ ID NO:1, instead the issue is that apart from further experimentation, the skilled artisan would not have been able to predict the structures of the full scope of the claimed polynucleotides, which retains the functionality encompassed by the instant invention, since functionality alone as recited in the instant claims does not elucidate the structure (e.g. nucleic acid sequence) of a polynucleotide having such function. See for example, MPEP § 2163, which states “[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” Therefore, it is the Examiner's position that while Applicant's adequately describe SEQ ID NO:1, which carries out the functionality of the instant claims, and thus have possession of SEQ ID NO:1, Applicant's do not adequately describe those polynucleotides sequences having at least 93% identity to SEQ ID NO:1, which carry out the functionality of the instant claims, and thus do not have possession of polynucleotides sequences having at least 93% identity to SEQ ID NO:1.

Applicants also argue that the instant specification discloses the human sequence upstream of the CARP gene (SEQ ID NO:2) and by comparing SEQ ID NO:2 with SEQ ID NO:1, one skilled in the art would know how to determine those sequences that are identical and thus conserved. Applicants contend that those conserved domains are “domains” or “regions” important to the function of the polypeptide and thus one skilled in the art would readily envision polynucleotides sequences having at least 93% identity to SEQ ID NO:1.

Applicant’s arguments and contentions have been fully considered but are not found persuasive because, as explained above, the issue at hand is not whether one skilled in the art can determine those polynucleotides sequences having at least 93% identity to SEQ ID NO:1, but is instead whether one skilled in the art can determine those polynucleotides sequences having at least 93% identity to SEQ ID NO:1, which are responsible for carrying out the functionality of the instant claims. The instant specification does not provide any structural detail or reference in the form of active domains or regions of SEQ ID NO:1, which carry out the function as instantly claimed. Given the fact that the instant specification does not provide enough structural detail such that one of skill in the art could envision those polynucleotides sequences having at least 93% identity to SEQ ID NO:1, which carry out the functionality as instantly claimed, it is reasonable to infer that the instant specification has not established a strong correlation between structure and function sufficient to satisfy the written description requirement. Accordingly, claims directed to polynucleotides sequences having at least 93% identity to SEQ ID NO:1, which carry out the function of inducing

expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide are rejected for lacking sufficient written description.

In summary, it is maintained that the instant specification does not disclose any correlation between the structure of the CARP gene, other than SEQ ID NO:1, and the claimed function of inducing expression in cardiac cells *in vivo*. Accordingly, one of skill in the art would be unable to discern from the specification those polynucleotides sequences having at least 93% identity to SEQ ID NO:1, which carry out the function of the claimed invention. Thus, because the distinguishing characteristics of the claimed polynucleotides are not described, one of skill in the art would not be apprised as what structural features those polynucleotides sequences having at least 93% identity to SEQ ID NO:1 have to induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide(s).

#### ***Claim Rejections - 35 USC § 102***

In the previous Office Action mailed January 4, 2006, claims 4, 5, 21, 23, 27, 31, 33, 39, 40, 41, 49, 50, 52, and 54-56 were rejected under 35 U.S.C. 102(b) as being anticipated by Kuo et al. (Development, 1999 Vol. 126:4223-4234). **This rejection is moot** against claims 4, 5, 21, 23, 27, 31, 33, and 39 in view of Applicant's Amendment filed March 28, 2006 to cancel these claims. **This rejection is withdrawn** against claims 40, 41, 49, 50, 52, and 54-56 in view of Applicant's Amendment filed March 28, 2006. Specifically, the Examiner is withdrawing this rejection in view of Applicant's

Amendment to recite, "wherein said polynucleotide comprises at least 92 nucleotides 3' to the transcription start position +1". It is noted that the p2.5Luc construct disclosed by Kuo et al. only contains only 47 nucleotides 3' to the transcription start position +1.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

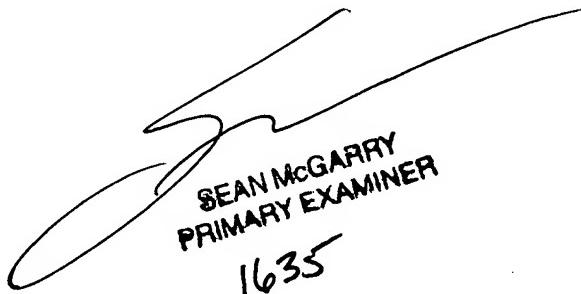
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg  
June 1, 2006



SEAN McGARRY  
PRIMARY EXAMINER  
1635

A handwritten signature of "Sean McGarry" is written over a stylized, swooping line. Below the signature, the words "PRIMARY EXAMINER" are printed in capital letters. Underneath "PRIMARY EXAMINER", the number "1635" is handwritten.